

WE CLAIM:

- 1 1. A stable bupropion hydrochloride tablet, wherein the tablet is free of stabilizer
2 and contains at least about 80% of undegraded bupropion hydrochloride after
3 storage for two months at 40°C and 75% relative humidity.
- 1 2. The tablet according to claim 1, wherein the tablet is a sustained release tablet.
- 1 3. The tablet according to claim 1, wherein the tablet comprises bupropion
2 hydrochloride, one or more release rate controlling polymers, and one or more
3 diluents, binders, lubricants, glidants and coloring agents.
- 1 4. The tablet according to claim 3, wherein the release rate controlling polymers
2 comprises one or more of cellulose derivatives, acrylates,
3 polyvinylacetate/povidone mixtures, polyethylene oxides, starches and their
4 derivatives, gums, alginates, carbohydrate based polymers, polysaccharide, and
5 combinations thereof.
- 1 5. The tablet according to claim 4, wherein the cellulose derivative comprises one
2 or more of ethyl cellulose, methylcellulose, hydroxymethylcellulose,
3 hydroxyethylcellulose, hydroxypropylcellulose, hydroxypropyl methylcellulose,
4 sodium carboxymethylcellulose, and combinations thereof.
- 1 6. The tablet according to claim 5, wherein the cellulose derivative comprises
2 hydroxypropyl cellulose.
- 1 7. The tablet according to claim 4, wherein the acrylate comprises one or more of
2 carbomer, polycarbophil, and EUDRAGIT®.
- 1 8. The tablet according to claim 7, wherein the carbomer comprises one or more of
2 Carbopol® -971 P, 974 P, and 934 P.
- 1 9. The tablet according to claim 3, wherein the binder comprises one or more of
2 starch, gelatin, highly dispersed silica, mannitol, lactose, polyethylene glycol,
3 polyvinylpyrrolidone, cross-linked polyvinylpyrrolidone, cross-linked

- 4 carboxymethyl cellulose, hydroxypropyl methylcellulose, hydroxypropyl
5 cellulose and natural, and synthetic gums.
- 1 10. The tablet according to claim 3, wherein the diluent comprises microcrystalline
2 cellulose.
- 1 11. The tablet according to claim 3, wherein the lubricant comprises stearic acid.
- 2 12. A method of stabilizing bupropion hydrochloride tablets using a dry granulation
3 process, the dry granulation process comprising:
4 a) blending bupropion hydrochloride and one or more pharmaceutically
5 acceptable excipient(s),
6 b) compacting or slugging the material of step (a),
7 c) sizing the compacted or slugged material of step (b) into granules, and
8 d) compressing the granules of step (c).
- 1 13. The method according to claim 12, wherein the tablet contains at least about 80%
2 of undegraded bupropion hydrochloride after storage for two months at 40°C and
3 75% relative humidity.
- 1 14. The method according to claim 12, wherein step (b) comprises compaction.
- 1 15. The method according to claim 14, wherein the compaction comprises using a
2 roller compactor.
- 1 16. The method according to claim 12, wherein step (c) comprises milling.
- 2 17. The method according to claim 12, further comprising lubricating the sized
3 granules of step (c) before compressing the granules.
- 1 18. The method according to claim 12, further comprising coating the tablet after
2 compressing the granules.

- 1 19. The method according to claim 12, wherein the one or more pharmaceutically
2 acceptable excipients comprise one or more of release rate controlling polymers,
3 diluents, binders, lubricants, glidants, and coloring agents.
- 1 20. The method according to claim 19, wherein the release rate controlling polymers
2 comprise one or more of cellulose derivatives, acrylates,
3 polyvinylacetate/povidone mixtures, polyethylene oxides, starches and their
4 derivatives, gums, alginates, carbohydrate based polymers, polysaccharide, and
5 combinations thereof.
- 1 21. The method according to claim 20, wherein the cellulose derivative comprises
2 one or more of ethyl cellulose, methylcellulose, hydroxymethylcellulose,
3 hydroxyethylcellulose, hydroxypropylcellulose, hydroxypropyl methylcellulose,
4 sodium carboxymethylcellulose, and combinations thereof.
- 1 22. The method according to claim 21, wherein the cellulose derivative comprises
2 hydroxypropyl cellulose.
- 1 23. The method according to claim 20, wherein the acrylate comprises one or more
2 of carbomer, polycarbophil, and EUDRAGIT®.
- 1 24. The method according to claim 23, wherein carbomer comprises one or more of
2 Carbopol® -971 P, 974 P and 934 P.
- 1 25. The method according to claim 19, wherein the binder comprises one or more of
2 from starch, gelatin, highly dispersed silica, mannitol, lactose, polyethylene
3 glycol, polyvinylpyrrolidone, cross-linked polyvinylpyrrolidone, cross-linked
4 carboxymethyl cellulose, hydroxypropyl methylcellulose, hydroxypropyl
5 cellulose, and natural or synthetic gums.
- 1 26. The method according to claim 19, wherein the diluent comprises
2 microcrystalline cellulose.
- 1 27. The method according to claim 19, wherein the lubricant comprises stearic acid.

- 1 28. The method according to claim 12, wherein the bupropion hydrochloride tablets
2 are free of stabilizer.
- 1 29. A method of one or both of treating depression and providing smoking cessation,
2 the method comprising:
- 3 providing bupropion hydrochloride in a dosage form,
4 wherein the dosage form is free of stabilizer and contains at least about 80% of
5 undegraded bupropion hydrochloride after storage for two months at 40°C and
6 75% relative humidity.
- 1 30. The method of claim 29, wherein the dosage form is produced using a dry
2 granulation process, the dry granulation process comprising (a) blending
3 bupropion hydrochloride and one or more pharmaceutically acceptable
4 excipients, (b) either compacting or slugging the blend of step (a), sizing the
5 compacted or slugged material of step (b) into granules, and (d) compressing the
6 granules of step (c).